General

Guideline Title

HIV testing during pregnancy and at delivery.

Bibliographic Source(s)

New York State Department of Health. HIV testing during pregnancy and at delivery. New York (NY): New York State Department of Health; 2011 Sep. 6 p. [9 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The quality of evidence (I-III) and strength of recommendation (A-C) are defined at the end of the "Major Recommendations" field.

New York State Public Health Regulations

The following are mandated in New York State (NYS) and must be performed in accordance with State Law:

All prenatal care settings regulated by the New York State Department of Health (NYSDoH), including hospitals, diagnostic and treatment centers, health maintenance organizations, and birthing centers, must provide human immunodeficiency virus (HIV) information and recommend HIV testing, preferably at the first prenatal visit for all women who present for care.

Diagnostic HIV tests must be performed in full compliance with the NYS Law .

If a woman presents for delivery without documentation of a negative HIV test during the current pregnancy and is not known to be HIV-infected, HIV expedited testing must be conducted on the mother with her consent:

- If the woman declines expedited testing, the newborn must be tested using the infant's blood specimen collected at birth. Maternal consent is not required.
- Results of expedited testing must be available as soon as possible, preferably within 1 hour, and no longer than 12 hours after the mother's consent or the infant's birth if the mother declines testing.

Preliminary positive expedited HIV test results obtained using HIV rapid testing or a laboratory-based screening test must be confirmed according to currently recommended procedures for diagnosing HIV infection.

- Confirmatory test results should be available as soon as possible and no later than 4 days after the preliminary positive HIV test result.
- Positive maternal confirmatory test results must be reported in accordance with NYS Law, which necessitates name reporting and partner notification.

HIV Testing During Third Trimester of Pregnancy

Clinicians should:

- Routinely recommend repeat testing in the third trimester, preferably between 34 and 36 weeks, for all women who test negative for HIV early in pregnancy. Repeat testing is strongly recommended for women who have continued high-risk behaviors during pregnancy or who acquire any other sexually transmitted infections during pregnancy.
- Offer testing during labor and delivery for any woman who does not have documented third trimester HIV test results. (AIII)

Clinicians should maintain a high level of suspicion for acute HIV infection in all pregnant women who present with a compatible clinical syndrome. Women who present with symptoms suggestive of acute HIV infection should be tested immediately, even if a previous HIV antibody test during current pregnancy was negative. Screening for acute infection can be performed by obtaining the following (AIII):

- An HIV serologic screening test in conjunction with a plasma HIV ribonucleic acid (RNA) assay. The plasma RNA test should be performed even if the serologic screening test is negative. If available, a fourth-generation HIV antigen/antibody combination test is the preferred serologic screening test.

Detection of HIV RNA or antigen in the absence of HIV antibody should be considered a preliminary positive result; HIV RNA testing from a new specimen should be repeated immediately (see the National Guideline Clearinghouse [NGC] summary of the NYSDoH guideline Acute HIV Infection in Pregnancy for more information.

NYS Law requires clinicians to discuss partner notification with patients who have been recently diagnosed with HIV infection. Assistance with partner notification can be provided through direct referral to the NYS and County Health Department Partner Services (PS) Programs, and the New York City Department of Health Contact Notification Assistance Program (CNAP). The partner notification discussion must be documented in the medical record and on the Medical Provider Reporting Form (DOH Form # 4189) as required by Public Health Law, Article 21, Title III, Section 213. (More information on partner notification assistance and resources can be found at: Partner Services outside of NYC or Contact Notification Assistance Program [CNAP]).

Evaluation and Management of Women Presenting in Labor Without Documentation of a Negative HIV Test During the Current Pregnancy and Who Are Not Known to Be HIV-Infected

All birth facilities should adopt point-of-care rapid HIV testing in labor and delivery settings for women who present in labor without documentation of a negative HIV test result during the current pregnancy and who are not already known to be HIV-infected. As per NYS Regulations, these women must receive expedited HIV testing or the infant must be tested at birth if the mother declines testing.

Facilities should perform expedited HIV testing using a U.S. Food and Drug Administration (FDA)-approved HIV rapid test; however, a conventional, laboratory-based screening test, such as an enzyme immunoassay (EIA) or chemiluminescent immunoassay (CIA), may be used if results can be returned rapidly, preferably within 1 hour, and no longer than 12 hours. The most sensitive screening test available should be used to allow for detection of early or acute HIV infection.

Facilities should strive to have expedited HIV test results available prior to delivery to allow maximum benefits of intrapartum antiretroviral (ARV) prophylaxis for the fetus.

When maternal expedited HIV testing yields a preliminary positive result, the clinician should:

- Discuss the meaning of a preliminary positive HIV test result with the mother. (AIII)
- Recommend immediate initiation of ARV prophylaxis during labor for the mother and for the infant in the immediate postnatal period, preferably within the first 6 to 12 hours, until HIV infection is definitively excluded. (AIII) (In this instance, the benefits of HIV prophylaxis given for a short period of time outweigh the risks of the medications). If a woman chooses to decline ARV prophylaxis for herself or her newborn, she should be educated about the benefits that ARV prophylaxis provides.
- Inform the mother about the risk of postpartum mother-to-child transmission (MTCT) via breast milk and that breastfeeding is contraindicated, even while receiving ARV prophylaxis, until there is definitive evidence that the mother is not infected with HIV. (Rousseau et al., 2003) (AII) Safe formula alternatives are available in the US; however, for women who wish to breastfeed, pumping and discarding or saving breast milk can be recommended to prevent breast engorgement and to continue milk production if HIV infection is definitively excluded by diagnostic tests that are capable of detecting early infection.

- Discontinue maternal ARV prophylaxis after delivery. If definitive test results indicate HIV infection, follow-up evaluation should occur by a provider who has experience with HIV management to discuss initiation of antiretroviral therapy.

NYS Regulations require that providers must obtain a confirmatory test for all preliminary positive HIV test results. Current recommendations require that a Western blot be obtained if the screening test produces a preliminary positive result, regardless of the type of screening test performed (rapid or EIA/CIA). If the Western blot is negative or indeterminate, a nucleic acid test (NAT) should be performed as soon as possible to distinguish between early HIV infection and a false-positive screening test result.*

When the definitive test results indicate HIV infection is present:

- ARV prophylaxis with at least zidovudine for the infant should be continued for 6 weeks. (AI) The infant should be discharged from the birth facility with the full 6-week supply of ARV prophylaxis.
- The importance of not breastfeeding should be emphasized. The infant should be discharged with a supply of formula.
- Arrangements should be made prior to discharge for the infant to receive HIV-related follow-up care from, or in consultation with, a pediatric provider who has experience with HIV management. This includes making arrangements for diagnostic testing to determine the infant's HIV status. The first diagnostic specimen should be sent within 48 hours of birth to the Pediatric HIV Testing Service at the Wadsworth Center, NYSDoH (see the NYSDoH guideline Diagnosis of Pediatric HIV Infection in HIV-Exposed Infants).
- Arrangements should be made prior to discharge, if possible, for the mother to receive follow-up evaluation by a provider who has experience with HIV management to discuss maternal health and future antiretroviral therapy (ART); referral should be made for subsequent HIV primary care. (AIII)
- Referral should be made for HIV-specific case management and supportive services.
- It should be explained to the mother that a confirmed positive antibody test result obtained from the infant is not reported unless the infant's HIV virologic assay (i.e., NAT, a general term which includes deoxyribonucleic acid polymerase chain reaction [DNA PCR] and RNA virologic assays) is positive (see the NYSDoH guideline Diagnosis of Pediatric HIV Infection in HIV-Exposed Infants).

After HIV infection has been definitively excluded in the mother:

- Infant ARV prophylaxis should be discontinued. (AI)
- Maternal ARV prophylaxis should be discontinued after delivery. (AI)
- Mothers may initiate breastfeeding if desired. (AII)

*An alternative diagnostic strategy that uses a combination of FDA-approved immunoassays and NAT to determine HIV infection status without Western blot testing has been proposed (Pandori & Branson, 2010) and may provide a more definitive result in less time; however, formal recommendations are required before laboratories can implement this alternative strategy for expedited maternal testing.

Key Point:

The ideal time for providing HIV information and testing in pregnancy is as early as possible. The peripartum period is the final opportunity to provide ARV prophylaxis and decrease the risk for MTCT to HIV-exposed infants in mothers who have not been previously identified as HIV-infected.

Definitions:

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

- Human immunodeficiency virus (HIV) infection
- Pregnancy
- Labor and delivery

Guideline Category

Counseling

Diagnosis

Management

Prevention

Screening

Clinical Specialty

Allergy and Immunology

Family Practice

Infectious Diseases

Internal Medicine

Obstetrics and Gynecology

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Health Care Providers

Nurses

Physician Assistants

Physicians

Public Health Departments

Guideline Objective(s)

To provide guidelines for human immunodeficiency virus (HIV) testing during pregnancy and at delivery

Target Population

- Pregnant women presenting to a hospital or a diagnostic or birthing center regulated by the New York State Department of Health
- Newborn infants of women with suspected or confirmed human immunodeficiency virus (HIV) infection

Interventions and Practices Considered

1. Providing human immunodeficiency virus (HIV) information and testing to pregnant women in accordance with New York State law
2. Repeat HIV testing during the third trimester of pregnancy
3. Testing during labor and delivery for any woman who does not have documented third trimester HIV test results
4. Testing of pregnant women presenting with symptoms suggestive of acute HIV infection
5. Use of an HIV serologic screening test in conjunction with a plasma HIV ribonucleic acid (RNA) assay
6. Discussing partner notification with patients recently diagnosed with HIV infection
7. Expedited HIV testing in labor and delivery settings for women without documentation of a negative HIV test result during the current pregnancy and who are not already known to be HIV-infected
8. Counseling pregnant patients on the meaning of a positive HIV test result
9. Immediate initiation of antiretroviral prophylaxis during labor for the mother and for the infant in the immediate postnatal period until HIV infection is definitively excluded
10. Informing the mother about the risk of postpartum mother-to-child transmission via breast milk and that breastfeeding is contraindicated
11. Discontinuation of maternal antiretroviral prophylaxis after delivery
12. Obtaining a confirmatory test for all preliminary positive HIV test results
13. Continuation of antiretroviral prophylaxis with at least zidovudine for the infant for 6 weeks
14. Follow-up care for infant and mother

Major Outcomes Considered

- Sensitivity and specificity of diagnostic tests
- Effectiveness of prophylaxis
- Number of newborns infected with human immunodeficiency virus (HIV)

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Primary Sources)

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Some areas of this guideline are based on New York State regulation and public health law. For recommendations formulated based on evidence rather than regulation or law, MEDLINE was searched up to January 2011 with use of appropriate key words. New York State laboratory data and epidemiologic data were also used. Human immunodeficiency virus (HIV) perinatal transmission guidelines from the Public Health Service Task Force and American College of Obstetrics and Gynecology were reviewed, as well as HIV testing guidelines from the Centers for Disease Control and Prevention.

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus (Committee)

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Quality of Evidence for Recommendation

I. One or more randomized trials with clinical outcomes and/or validated laboratory endpoints
II. One or more well-designed, non-randomized trials or observational cohort studies with long-term clinical outcomes
III. Expert opinion

Methods Used to Analyze the Evidence

Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

AIDS Institute clinical guidelines are developed by distinguished committees of clinicians and others with extensive experience providing care to people with human immunodeficiency virus (HIV) infection. Committees* meet regularly to assess current recommendations and to write and update guidelines in accordance with newly emerging clinical and research developments.

The Committees* rely on evidence to the extent possible in formulating recommendations. When data from randomized clinical trials are not available, Committees rely on developing guidelines based on consensus, balancing the use of new information with sound clinical judgment that results in recommendations that are in the best interest of patients.

*Current committees include:

- Medical Care Criteria Committee
- Committee for the Care of Children and Adolescents with HIV Infection
- Dental Standards of Care Committee
- Mental Health Guidelines Committee
- Committee for the Care of Women with HIV Infection
- Committee for the Care of Substance Users with HIV Infection
- Physicians' Prevention Advisory Committee
- Pharmacy Advisory Committee

Rating Scheme for the Strength of the Recommendations

Strength of Recommendation

A. Strong recommendation for the statement
B. Moderate recommendation for the statement
C. Optional recommendation

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

External Peer Review

Description of Method of Guideline Validation

All guidelines developed by the Committee are externally peer reviewed by at least two experts in that particular area of patient care, which ensures depth and quality of the guidelines.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Pandori MW, Branson BM. 2010 HIV Diagnostics Conference. Expert Rev Anti Infect Ther. 2010 Jun;8(6):631-3. PubMed

Rousseau CM, Nduati RW, Richardson BA, Steele MS, John-Stewart GC, Mbori-Ngacha DA, Kreiss JK, Overbaugh J. Longitudinal analysis of human immunodeficiency virus type 1 RNA in breast milk and of its relationship to infant infection and maternal disease. J Infect Dis. 2003 Mar 1;187(5):741-7. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate human immunodeficiency (HIV) testing during pregnancy and at delivery and timely prophylaxis in women identified as HIV-infected, thus preventing mother-to-child HIV transmission

Potential Harms

Human immunodeficiency virus (HIV) testing could render false-positive results.

Contraindications

Contraindications

Breastfeeding is contraindicated, even while receiving antiretroviral (ARV) prophylaxis, until there is definitive evidence that the mother is not infected with human immunodeficiency virus (HIV).

Qualifying Statements

Qualifying Statements

When formulating guidelines for a disease as complex and fluid as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), it is impossible to anticipate every scenario. It is expected that in specific situations, there will be valid exceptions to the approaches offered in these guidelines and sound reason to deviate from the recommendations provided within.

Implementation of the Guideline

Description of Implementation Strategy

The AIDS Institute's Office of the Medical Director directly oversees the development, publication, dissemination and implementation of clinical practice guidelines, in collaboration with The Johns Hopkins University, Division of Infectious Diseases. These guidelines address the medical management of adults, adolescents and children with human immunodeficiency virus (HIV) infection; primary and secondary prevention in medical settings; and include informational brochures for care providers and the public.

Guidelines Dissemination

Guidelines are disseminated to clinicians, support service providers and consumers through mass mailings and numerous AIDS Institute-sponsored educational programs. Distribution methods include the HIV Clinical Resource website, the Clinical Education Initiative (CEI), the AIDS Educational Training Centers (AETC) and the HIV/AIDS Materials Initiative. Printed copies of clinical guidelines are available for order from the New York State Department of Health (NYSDoH) Distribution Center.

Guidelines Implementation

The HIV Clinical Guidelines Program works with other programs in the AIDS Institute to promote adoption of guidelines. Clinicians, for example, are targeted through the CEI and the AETC. The CEI provides tailored educational programming on site for health care providers on important topics in HIV care, including those addressed by the HIV Clinical Guidelines Program. The AETC provides conferences, grand rounds and other programs that cover topics contained in AIDS Institute guidelines.

Support service providers are targeted through the HIV Education and Training initiative which provides training on important HIV topics to non-physician health and human services providers. Education is carried out across the State as well as through video conferencing and audio conferencing.

The HIV Clinical Guidelines Program also works in a coordinated manner with the HIV Quality of Care Program to promote implementation of HIV guidelines in New York State. By developing quality indicators based on the guidelines, the AIDS Institute has created a mechanism for measurement of performance that allows providers and consumers to know to what extent specific guidelines have been implemented.

Finally, best practices booklets are developed through the HIV Clinical Guidelines Program. These contain practical solutions to common problems related to access, delivery or coordination of care, in an effort to ensure that HIV guidelines are implemented and that patients receive the highest level of HIV care possible.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Timeliness

Identifying Information and Availability

Bibliographic Source(s)

New York State Department of Health. HIV testing during pregnancy and at delivery. New York (NY): New York State Department of Health; 2011 Sep. 6 p. [9 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2011 Sep

Guideline Developer(s)

New York State Department of Health - State/Local Government Agency [U.S.]

Source(s) of Funding

New York State Department of Health

Guideline Committee

Perinatal Transmission Committee

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Financial Disclosures/Conflicts of Interest

Not stated

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the New York State Department of Health AIDS Institute Web site .

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on January 30, 2012.

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